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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,801	10/16/2003	Graham P. Allaway	1900.0380001	5154

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EXAMINER	
PENG, BO	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,801	ALLAWAY ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.
4a) Of the above claim(s) *19* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-18 and 20-27* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date *5/7/04*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bo Peng, Art Unit 1648.

Restriction election

2. The Office acknowledges the receipt of Applicant's restriction election filed on January 30, 2006. Applicant elects Group I, claims 1-6, 8, 9, 14-18 and 20-27, the species HIV, with traverse. The traversal is on the ground(s) that Groups I-III have not been demonstrated to be independent or distinct because 1) claim 1 is generic and encompasses the use of an antibody and antibody fragment of Group I and a peptide of Group II; and 2) claim 10 of Group III includes an additional element in the claimed assay of claim 1, thus Groups I-III should be related as combination/sub-combination.

3. Upon consideration of applicant's arguments, the restriction requirement between Groups I-III has been withdrawn. The prior art search has been extended to include claims 7 and 10-13. Accordingly, claims 1-27 are pending. Claim 19 is withdrawn from consideration as being directed to a non-elected invention. Claims 1-18 and 20-27 are examined to the extent of HIV as the elected species in the instant Office action. This restriction is made FINAL.

Specification

4. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed

applications in the specification should also be updated where appropriate.

Information Disclosure Statement

5. The information disclosure statement submitted on May 7, 2004 is in compliance with the provisions of 37 CRF 1.97. Accordingly, the information disclosure statement has been considered by the examiner. An initialed and dated copy of Applicant's IDS form 1449 is attached to the instant Office action.

Claim Rejections - 35 USC § 112, first paragraph-Written Description

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-18 and 20-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession at the time the invention was made, of the specific subject matter claimed. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008,

> 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

9. Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

10. MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two

chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

11. The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

12. In the instant case, claims 1-18 are 20-27 are drawn to a method for identifying compounds that decrease the ability of a virus to infect uninfected cells, comprising: provide a cell, virion, pseudovirion, membrane vesicle, lipid bilayer, or liposome expressing or bearing viral envelope protein or glycoprotein or fragment thereof, contact said the cell, virion, pseudovirion, membrane vesicle, lipid bilayer, or liposome with a candidate compound; and measure the ability of said candidate compound to induce conformational changes in viral envelope glycoprotein by determining binding of an antibody, antibody fragment or peptide to said viral envelope glycoprotein or fragment thereof, wherein the said virus is HIV.

13. Since there is no limitation to a virus, the scope of claim 1 encompasses a method for identifying compound the decrease the ability of any known and unknown viruses, comprising: providing a cell, virion, pseudovirion, membrane vesicle, lipid bilayer, or liposome expressing or bearing unspecified viral envelope protein or glycoprotein or fragment thereof, and measure the ability of said candidate compound to induce conformational changes in viral envelope

glycoprotein by determining binding of unspecified antibody, antibody fragment or peptide to said viral envelope glycoprotein or fragment thereof. Although applicant discloses H9 cells expressing HIV envelope protein in the specification, Applicant has not disclosed sufficient species of cells, virions, pseudovirions, membrane vesicles, lipid bilayers, or liposomes expressing HIV envelope or glycoproteins or fragments thereof, nor cells, virions, pseudovirions, membrane vesicles, lipid bilayers, or liposomes bearing unspecified viral envelope proteins or glycoproteins or fragments thereof to support the broadly claimed genus of all constructs bearing unspecified viral envelope proteins and fragments, nor all conformation-specific antibodies against all viruses. Consequently, while the skilled artisan would reasonably conclude Applicant was in possession of H9 cells expressing HIV envelope proteins, there is no indication that Applicant was in possession of all cells, virions, pseudovirions, membrane vesicles, lipid bilayers, or liposomes bearing HIV envelope protein or other unspecified viral envelope proteins or glycoproteins or fragments thereof as broadly claimed, as well as all conformation-specific antibodies against all viruses.

14. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 112, first paragraph-Scope of Enablement

15. Claims 1-18 and 20-27 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying compounds that decrease the ability of HIV to infect uninfected cells using H9 cell expressing HIV envelope, does not reasonably provide enablement for a method for identifying compounds that decease the ability of all other known and unknown viruses to bind to their antibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech Inc. v. Novo Nordisk 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); In re Wright 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); In re Fisher 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in In re Wands 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman [230 USPQ 546, 547 (BdPatApplnt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

16. Since there is no limitation to "a virus" in claim 1, the claim limitation encompasses any known and unknown viruses. However, the only working example given in the specification is a method for detecting compounds that affect the formation of HIV transient fusion intermediates. The specification has not disclosed any sequences, regions and structures of all claimed viruses that are associated with the formation of transient fusion intermediates, resulting in the virus entry. The specification has not disclosed any antibodies that can target such transient fusion intermediates of all claimed viruses. There is no evidence that the antibodies, such as T26, 17b, 48d, 8F101 or A32, which target HIV-1 gp41 six-helix bundle structure, can be used for evaluating the conformational changes of all other viruses. Although the skill in the art is high, it takes **undue** amount of experimentation to identify such transient fusion intermediates of all claimed viruses, and takes **undue** amount of experimentation to screen and test antibodies against such transient fusion intermediates of all claimed viruses.

17. Since the limitation in claim 1 clearly covers a very broad range of viruses, in view of the empirical and unpredictable nature of the invention with regard to antiviral drug screening for all viruses, and lack of guidance and working examples in the specification, one skilled in the art cannot practice the claimed invention without undue experimentation. The instant invention, based on the evidence as a whole, in light of the factors articulated by the court in *In re Wands*, lacks an enabling disclosure.

Double Patenting

18. Claims 1-18 and 20-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,605,427. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to same process using same products.

19. Claims 1-18 and 20-25 are drawn to a method for identifying compounds that decrease the ability of a virus to infect uninfected cells, comprising: provide a cell, virion, psudovirion, membrane vesicle, lipid bilayer, or liposome expressing or bearing viral envelope protein or glycoprotein or fragment thereof, contact said cell, virion, psudovirion, membrane vesicle, lipid bilayer, or liposome with a candidate compound; and measure the ability of said candidate compound to induce conformational changes in viral envelope glycoprotein by determining binding of an antibody, antibody fragment or peptide to said viral envelope glycoprotein or fragment thereof, wherein the said virus is HIV, wherein said contact of said cell, virion, pseudovirion, membrane vesicle, or lipid bilayer with a candidate compound optionally occurs in the presence of one or more cellular receptors or fragments thereof for said virus, wherein said cellular receptors are selected from the group consisting of CD4, fragments of CD4, chemokine receptors CCR5 or CXCR4, and combinations thereof.

20. Claims 1-3 of US patent 6,605,427 are drawn to a method for determining the effect of a test compound on the formation of a conformational intermediate of viral entry and/or fusion, comprising contacting a viral envelope protein or glycoprotein with a triggering agent and a candidate compound to form a mixture, and thereafter measuring the effect that the test compound has on the formation of said conformational intermediate is measured by incubating

said mixture with specific antibodies to determine whether the amount of antibody binding to a conformational intermediate of viral entry is increased or decreased due to the presence of the test compound, wherein said viruses are HIV-1, HIV-2, HTLV-1, RSV, HPIV-3, FIV, human influenza viruses or measles virus. Claims 4-19 further comprises one or more virus permissive cells, one or more insoluble or soluble receptors from said virus permissive cells, or a combination thereof, wherein said permissive cells are one or more lymphocytes, or one or more insoluble or soluble receptors from said lymphocytes.

21. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use a method for identifying compounds that decrease the ability of a virus to infect uninfected cells by contact the compound with HIV envelope-expressing constructs, such as a cell, virion, pseudovirion, membrane vesicle, lipid bilayer, or liposome expressing or bearing viral envelope protein in the assay because 6,605,427 teaches is within the skill of the art to determine the effect of a test compound on the formation of a conformational intermediate of viral entry and/or fusion using a viral envelope protein or glycoproteins with a lipid bilayer that is provided in the form of cells, virions, pseudovirions, membrane vesicles or liposomes (6,605,427, claims 5, 10 and 13) and to measure the formation of said conformational intermediate is measured by incubating said mixture with specific antibodies to determine whether the amount of antibody binding to a conformational intermediate of viral entry is increased or decreased due to the presence of the test compound (6,605,427 claims 1-4).

22. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to further comprise one or more cellular receptors, like CD4 and CCR5 or CXR4, into the claimed assay because 6,605,427 teaches it is within the skill of the art

to incorporate one or more lymphocytes, or one or more insoluble or soluble receptors from said lymphocytes (claims 5 and 13). One of ordinary skill in the art knows at the time the invention was made that CD4, CCR5, are CXCR4 naturally expressed on the surface lymphocytes are involved in HIV entry to cells. Therefore, the instant invention as a whole is the same process using the same products as 6,605,427.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 1-18 and 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,605,427 and Liang (1998 & 1999).

25. Claim 1-18 and 20-17 read on a method for identifying compounds that decrease the ability of HIV-1 to infect previously uninfected cells, comprising: provide HIV-1 envelope glycoproteins gp120/gp41 or fragments thereof in association with a cell, virion, pseudovirion, membrane vesicle, lipid bilayer, or liposome; contact said HIV-1 envelope glycoproteins gp120/gp41 or fragments thereof with a candidate compound; and measure the ability of said candidate compound to induce changes that result in the formation of entry structures in gp41, wherein the ability of said candidate compound to induce said conformational changes in gp41 is detected by using polyclonal and/or monoclonal sera raised against peptides, a mixture of

peptides, or proteins mimicking gp41 conformational structures, wherein the ability of said candidate compound to induce said conformational changes in gp41 is detected by using polyclonal sera generated by immunizing animals with a 1:1 mixture of the P15 and P16 peptides, wherein the ability of said candidate compound to induce said conformational changes in gp41 is detected by using monoclonal antibodies including, T26, 17b, 48d, 8F101 or A32, or mixtures thereof.

26. The relevance of 6,605,427 is given above.

27. Liang (1999) teaches a screening assay for antiviral compound targeted to conformational changes of HIV gp41 by detecting the formation of a complex formation by N and C-peptides and a conformation-specific monoclonal antibody in the presence of the test compounds.

28. Liang teaches that immunization BALB/c mice with N36(L6)C34, which is a stable subdomain consisting of two peptide N36 and C34. Liang teaches that N-36 and C-43 mixed at equimolar concentrations form stable α-helical trimer of antiparallel heterodimer, representing the fusion-active core domain of gp41 (see Liang 1999, last paragraph, column 1, p.86). It is noted that N36 is identical to P15 peptide and C34 is identical to P16 of the instant invention (see Liang 1999, Fig.1, p. 87; also see specification in Pre-Grant Publication, page 16, P15 peptide of SEQ ID NO: 3 and P16 peptide of SEQ ID NO:6). Liang's N36(L6)C34 peptide consists of N-36 and C-34 connected in 1:1 ratio by a six-residue hydrophilic linker, which folds into a minimal six-helix core. Liang identifies a monoclonal antibody, designed as NC-1, from the sera of the animals immunized with N36(L6)C34 peptide that can specifically bind to the conformational epitopes on the six-helix core of gp41. Liang teaches assessing the binding activity of the antibody in the mouse sera to a peptide or protein antigen (see Liang 1998, last

paragraph, p. 10213 to column 1, p. 10216, Fig. 2, 3 and 4 and 5). Since there is no limitation in the instant claims to candidate compounds and antibody or peptides used for bind to the compounds, Liang's NC-1 meets the limitations of the instant claims as a conformation-specific antibody as it is used in the screens assay (Liang 1998), and as an antiviral compound as described in Liang 1999.

29. Liang does not explicitly teach assessing the binding activity of NC-1 (as a compound) generated from the mouse sera to a protein antigen in the presence of other monoclonal antibodies including T26, 17b, 48d, 8F101 or A32.

30. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to identify compounds in the polyclonal sera generated by immunizing animals with P15 and P16 in the presence of other antibodies because Liang teaches it is within the skill of the art to generate anti-fusion intermediate antibodies using six-helix bundle mimics, and because 6,605,427 teaches it is within the skill of the art to measure the effect of the compound on the formation of conformational intermediate by specific gp41 antibodies. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success because Laing has shown a compound (antibody) that against gp41 fusion intermediate can be generated by immunizing animals with a six-helix bundle mimics, and T-26, 17b, 48d, 8F101, and A32 against gp41 are available and their biological properties are well characterized and recognized as gp41 conformation-specific antibodies in the art of HIV virology at the time the claimed invention was made (see specification, paragraphs 0068 and 0069, column 2, page 5). Thus, antibodies T-26, 17b, 48d, 8F101, and A32 are readily be used in the assay as taught by 6,605,427. Therefore, the invention as a whole was prima facie obvious over

US 6,605,427 and Liang.

Remarks

31. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

BP
Bo Peng, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER